

publication” more than one year prior to the date of the application for patent. Accordingly, the entire claimed invention must appear in a single printed publication in order to be a proper anticipation. Reconsideration and withdrawal of this rejection is therefore requested.

Kawasaki relates to a compressive hemostatic belt designed to apply pressure to an insertion wound to stop the bleeding. Accordingly, the Kawasaki belt is not an ostomy device, as it is not designed to control the passage of waste material through a surgically created opening in the body. It certainly is not designed to control the passage of solid waste material, as is required by the claims.

The preamble of each of the independent claims explicitly states that the invention is an ostomy device used to control the passage of liquid and solid waste through the stoma. Clearly, it is not liquid or solid waste, but instead blood, that escapes through a catheter insertion wound and which the Kawasaki belt is designed to control.

The body of each of the independent claims requires that the member of the device be adapted to prevent passage of “liquid and solid waste” material through the stoma when pressed against the stoma.

Applicant respectfully disagrees with the Examiner’s comment that “stoma”, even when that term is broadly defined as being a surgically created artificial opening in a human patient, would be construed by one skilled in the art to include a catheter insertion wound.

The fact that Kawasaki is a compressive hemostatic belt used to stop bleeding from a catheter insertion wound and therefore is not an “ostomy” device and does not

control the passage of liquid and solid waste, is itself enough to distinguish over Kawasaki.

The Examiner's argument that Kawasaki provides the motivation for the use of an adhesive seal that completely surrounds and encloses the stoma, as taught by Wagner, is quite incorrect. The purpose of Kawasaki is to apply pressure to the insertion wound to produce a hemostatic effect, that is, to stop the bleeding, so that the wound can heal. Using adhesive to attach the Kawasaki belt (balloon 5, pocket fabric 2 or gauze 10) directly to the skin surrounding the wound is counter-indicated because removal of such an adhesively attached hemostatic belt would result in reopening of the wound. The removal of the belt with an adhesive layer would cause the skin around the wound, which is attached to the belt by the adhesive layer, to move with the belt and tear open the wound. One skilled in the art would certainly know that and would certainly avoid the use of any adhesive in a hemostatic pressure belt.

That is why Kawasaki teaches, at Col. 9, line 24, that the adhesive plaster 14 is used to lock the end of the belt in place but does not contact the skin, as seen in Figure 22a and that the adhesive plaster 15 is applied to the skin along the edge of the belt which is remote from the wound itself, as seen in both Figs. 22a and 22b, to prevent movement of the belt relative to the body. Those plasters are used to secure Kawasaki's belt to the body, but are purposely situated at a location remote from the insertion wound, such that removal of the belt will not result in tearing the wound open.

Wagner and Lloyd do relate to ostomy devices. Accordingly, each teaches sealing the ostomy appliance to skin surrounding the stoma because, unlike an insertion wound

which is supposed to heal rapidly, the stoma is a permanent or semi-permanent opening which will not be torn opened by the removal of an adhesively mounted appliance.

No person skilled in the art would use an appliance that is adhesively attached around an insertion wound to apply pressure to the insertion wound to stop the bleeding. That is because the removal of such an appliance would result in tearing open the wound, the very opposite of the purpose of the appliance. As a result, the proposed combination is inappropriate and cannot support a rejection, under 35 USC 102(b) or under 35 USC 103(a).

Claims 41, 45 and 56, respectively rejected under 35 USC 103(a), are dependant upon Claim 35 and are believed to be patentable for the same reason as Claim 35.

Respectfully submitted,



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